Fact Sheet

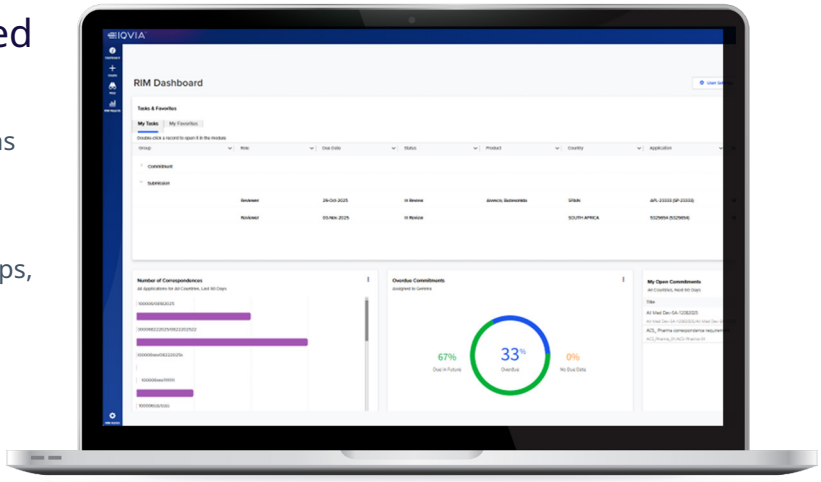
IQVIA SmartSolve® RIM Content Management for Pharma

Empower your regulatory teams to create and approve submission-ready documents at scale

SmartSolve RIM Content Management, an integral module in the IQVIA SmartSolve RIM platform, delivers a versatile SaaS solution to assemble augmented content for publishing efficiently and compliantly throughout the regulatory submission process.

Why choose a modern, cloud-based content management solution?

Reliance on simple fileshare and SharePoint solutions limits collaboration on submission content. Manual document management, including versioning and changes, reconciliation of renditions and relationships, is inefficient and may pose compliance risks.



SmartSolve RIM Content Management transforms submission content planning and production

QUALITY

Enhance the accuracy and consistency of documentation by fostering collaboration across all stakeholders

ACCELERATE

Streamline your workflows to accelerate content authoring, review and approval

REDUCE COSTS

Lower waste from errors in producing submission content

EFFICIENCY

Gain visibility into real-time task progress and potential timeline risks to keep submissions on track

COMPLIANCE

Deliver peace of mind by adhering to industry standards and ensuring GXP compliance throughout the content lifecycle

Support submission content and quality in a unified platform

SmartSolve RIM Content Management provides a single, authoritative source for all regulatory and quality documents. This unified ecosystem enables easy reuse of documentation and references, while keeping product metadata — such as regional market and study details — fully synchronized.

Submission content planning and publishing

- **Centralized access and search:** Easily access the staging area and efficiently search/filter documents using robust metadata and properties.
- **Submission integration:** Associate documents directly with submissions and download content to streamline regulatory publishing.
- **Comprehensive reporting:** View detailed reports on documents, their properties, and usage across submissions for full transparency.
- **Version control and migration:** Bind to specific document versions/renditions and seamlessly manage migration between versions.
- **Content management lifecycle:** Enables the structured process of handling documents from creation to disposal.
- **Standardize content consistency:** Leverage standardized authoring templates and define document types to streamline creation and enable consistent handling.

Control

- Manage regulatory documents across the lifecycle including timelines, relationships, permissions, and various renditions
- Monitor organizational usage with metrics for document production, authors and reviewers, etc.
- Organize documents based on Product, Application, Composition, Study data, etc.

Compliance

- Regulatory-ready with FDA's 21 CFR Part 11 requirements governing electronic records, audit trails, and digital signatures.
- Manage documents in accordance with industry -standard CTD and eCTD content structures.
- Minimize validation burden with a cloud-based solution.

Leverage the power of SmartSolve RIM with capabilities that support the Pharmaceutical and MedTech industries in a single, modular and scalable platform.

About SmartSolve®:

SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. SmartSolve® eQMS centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while SmartSolve® RIM manages regulatory submissions, product registrations, and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

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